AUG - 4 2008

K081859

Attachment 5 - 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h).

Submitter:

Sicel Technologies, Inc.
3800 Gateway Centre Blvd.
Suite 308
Morrisville, NC 27560

Contact: Suzanne Schwaller, Regulatory Affairs Associate
Phone: (919) 465-2236 ext. 363
Fax: (919) 465-0153

Prepared: June 27, 2008

Common or Usual Name: Radiation Dosimeter

Proprietary Name: OneDose Patient Dosimetry System

Classification Name: Accelerator, Linear, Medical

Manufactured By: Sicel Technologies, Inc.
3800 Gateway Centre Blvd.
Suite 308
Morrisville, NC 27560

Phone: (919) 465-2236
Fax: (919) 465-0153

Predicate Device(s):

Sicel Technologies, Inc.
K040687
OneDose Patient Dosimetry System

Device Description:

The OneDose Patient Dosimetry System consists of the following components and accessories: (1) disposable, single use, pre-calibrated radiation dosimeters, (2) a hand held, battery powered reader, (3) a reader calibration test strip and

(4) reader download software. The dosimeters use a MOSFET, metal oxide semiconductor field effect transistor as a sensing mechanism. The dosimeters are inserted into the Reader and zeroed, then positioned onto a patient. The dosimeters are small and have no wires. They have a medical grade adhesive and liner on the back. The liner is removed and the adhesive side of the dosimeter is adhered to the patient. Following radiotherapy, the dosimeters are removed from the patient, re-inserted into the Reader, and the patient's dose is read and reported by the Reader. The patient's records are stored on the dosimeter for future reference and in the Reader's memory.

Intended Use:

The OneDose Patient Dosimetry System is intended to measure a patient's dose during radiotherapy application.

Comparison with Predicate Device:

The intended use of this OneDose Patient Dosimetry System is identical to the predicate device, the OneDose Patient Dosimetry System as cleared in K040687.

The technological features of the OneDose Patient Dosimetry System are the same as the predicate including the use of MOSFET technology, the calibration method, the dose range for a single dose, the energy types measured, and the method of adhesion to the skin. The principle of operation is the same as the predicate. The primary difference between the predicate device and the modified device is the change in the accuracy specification, the addition of a dosimeter version with an integrated build-up cap, and the addition of a download software option which allows programming of the reader and creating of predefined reports. There are multiple material changes including minor changes to the dosimeter encapsulant, circuit board components and passivation layer and an addition of a grommet edging to the keypad connector. Minor changes dimensions were also implemented. Details of the substantial equivalence comparison are provided.

Furthermore, verification and validation testing provided information sufficient to determine that the modifications did not have an effect on safety or effectiveness and demonstrated that the device met pre-determined acceptance criteria based on performance specifications. The testing demonstrated that the modified device is substantially equivalent to the predicate device and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Suzanne M. Schwaller
Regulatory Affairs Associate
Sicel Technologies, Inc.
3800 Gateway Centre Blvd., Suite 308
MORRISVILLE NC 27560

AUG - 4 2008

Re: K081859
Trade/Device Name: OneDose Patient Dosimetry System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 30, 2008
Received: July 1, 2008

Dear Ms. Schwaller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 6 – Intended Use Statement

510(k) Number (if known): K081859

Device Name: OneDose Patient Dosimetry System

Intended Use:

The OneDose Patient Dosimeter System is intended to measure a patient's dose during radiotherapy applications. This intended use has not changed as a result of the modifications.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081859